

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION and
EXPANDABLE GRAFTS
PARTNERSHIP,

Plaintiffs,

v.

ADVANCED CARDIOVASCULAR
SYSTEMS, INC., GUIDANT
CORPORATION, ARTERIAL
VASCULAR ENGINEERING, INC.,
BOSTON SCIENTIFIC CORPORATION,
and SCIMED LIFE SYSTEMS, INC.

Defendants.

Civil Action No. 97-550-SLR
(Consolidated)



FILED

**ANSWER AND COUNTERCLAIMS OF DEFENDANT
ADVANCED CARDIOVASCULAR SYSTEMS, INC.**

Defendant Advanced Cardiovascular Systems, Inc. ("ACS"), hereby answers the Consolidated Complaint of Plaintiffs Cordis Corporation ("Cordis") and Expandable Grafts Partnership ("EGP") in the above-identified action as follows:

ANSWER

1. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint, and therefore, denies each and every one of those allegations.

2. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint, and therefore, denies each and every one of those allegations.

3. ACS admits that Advanced Cardiovascular Systems, Inc. is a corporation organized and existing under the laws of the State of California, and has its principal place of business in California. ACS admits that it is doing business by supplying its products within this judicial district. ACS denies each and every one of the remaining allegations contained in paragraph 3 of the Complaint.

4. ACS admits that Guidant Corporation is a corporation organized and existing under the laws of the State of Indiana. ACS denies each and every one of the remaining allegations contained in paragraph 4 of the Complaint.

5. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint, and therefore denies each and every one of those allegations.

6. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of the Complaint, and therefore denies each and every one of those allegations.

7. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the Complaint, and therefore denies each and every one of those allegations.

8. ACS admits that Cordis and EGP purport to bring this action under the Patent Laws of the United States, Title 35, United States Code, and under the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, but denies that this action properly arises under the Patent Laws or the Declaratory Judgment Act. ACS admits that Cordis and EGP purport to base jurisdiction on the statutes cited in paragraph 8 of the Complaint, but denies that jurisdiction over Cordis' and EGP's causes of action properly lies with this Court.

9. ACS denies that venue is proper for Advanced Cardiovascular Systems, Inc. and ACS denies that venue is proper for Guidant Corporation under the statutes cited in paragraph 9 of the Complaint.

10. ACS repeats and realleges each and every allegation of paragraphs 1 through 9 as though fully set forth herein.

11. Based upon information and belief, ACS admits that U.S. Patent No. 4,733,762 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft"(the "762 patent") issued on April 26, 1988, and that a copy of that patent was attached to the Complaint as Exhibit A.

12. Based upon information and belief, ACS admits that U.S. Patent No. 5,102,417 entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft"(the "417 patent") issued on April 7, 1992, and that a copy of that patent was attached to the Complaint as Exhibit B.

13. Based upon information and belief, ACS admits that U.S. Patent No. 5,195,984 entitled "Expandable Intraluminal Graft"(the "984 patent") issued on March 23, 1993, and that a copy of that patent was attached to the Complaint as Exhibit C.

14. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint, and therefore denies each and every one of those allegations.

15. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of the Complaint, and therefore denies each and every one of those allegations.

16. ACS denies that it has engaged in any act of infringement of the '762 patent and the '417 patent, and denies each and every one of the remaining allegation of paragraph 16 of the Complaint.

17. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17 of the Complaint, and therefore denies each and every one of those allegations.

18. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 18 of the Complaint, and therefore denies each and every one of those allegations.

19. ACS denies that Cordis and EGP have been, and continue to be, damaged by any purported infringement by ACS of the '762 and '417 patents. ACS is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 19 of the Complaint, and therefore denies each and every one of those allegations.

20. ACS denies that it has willfully infringed the '762 patent and the '417 patent. ACS is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 20 of the Complaint, and therefore denies each and every one of those allegations.

21. ACS repeats and realleges each and every allegation of paragraphs 1 through 20 as though fully set forth herein.

22. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the Complaint, and therefore denies each and every one of those allegations.

30. By reason of the state of the prior art, and proceedings in the U.S. Patent and Trademark Office during prosecution of the applications which resulted in the issuance of the '762 and '417 patents, including the amendments of claims and arguments and other statements made during the prosecution by or on behalf of the patentee, Cordis and EGP are estopped to assert that ACS has infringed or is infringing the '762 and '417 patents.

31. The '762 and '417 patents are both invalid for failure to comply with the requirements of Part II of Title 35 of the United States Code including, inter alia, the requirements of 35 U.S.C. §§ 102, 103, and 112.

32. Cordis and EGP are barred, in whole or in part, from recovery for alleged infringement by ACS by reason of Cordis' and EGP's failure to comply with the requirements of 35 U.S.C. § 287.

33. For having brought the action, Cordis and EGP are liable to ACS under 35 U.S.C. § 285.

34. The claims of the '762 and '417 patents are unenforceable as a result of inequitable conduct and/or fraud committed by Cordis and EGP in proceedings in the U.S. Patent and Trademark Office ("PTO"). In particular, U.S. Patent No. 4,733,665 and Reexamination Certificate No. B1 4,733,665 (collectively the "'665 patent") issued to Dr. Julio C. Palmaz ("Dr. Palmaz"), and all patents in the same chain including the '417 and '762 patents, are unenforceable in view of the inequitable conduct of Dr. Palmaz, his attorneys, and those substantively involved in the prosecution of the '665 patent for a number of misleading and wrongful acts designed to intentionally deceive the PTO. The misleading and wrongful acts include acts of omission of material information and affirmative acts all of which were designed with the requisite intent to deceive the PTO and included at least the following:

23. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the Complaint, and therefore denies each and every one of those allegations.

24. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 24 of the Complaint, and therefore denies each and every one of those allegations.

25. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 25 of the Complaint, and therefore denies each and every one of those allegations.

26. ACS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the Complaint, and therefore denies each and every one of those allegations.

AFFIRMATIVE DEFENSES

27. The Court should dismiss Cordis' and EGP's purported causes of action against Advanced Cardiovascular Systems, Inc. because Cordis lacks standing and improperly joined EGP, and Cordis cannot correct the jurisdictional defect *nunc pro tunc* by amending the Complaint in the original action or by this consolidated action.

28. Cordis and EGP are barred from any recovery by the equitable defense of laches.

29. ACS has not infringed and is not infringing, actively inducing others to infringe, or contributing to the infringement of the claims of the '762 and '417 patents under any theory of literal infringement or infringement under the doctrine of equivalents.

a. Failure to disclose to the PTO during prosecution of the '665 patent an abstract entitled Expandable Intraluminal Graft: A Preliminary Study, by Palmaz et al., which was publicly available in October 1984, more than one year before the patent application for the '665 patent was filed.

b. Submitting a false and misleading affidavit (with exhibits) of Dr. Palmaz during the First Reexamination of the '665 patent, including filing an affidavit under 37 C.F.R. 1.131 ("Rule 131") to antedate a prior art patent, namely, U.S. Patent No. 4,560,374 issued to Hammerslag. The Rule 131 affidavit stated that dog experiments were conducted in late 1983 and were supported with two manuscripts that were misdated by Dr. Palmaz, who now admits that those manuscripts were misdated. The Rule 131 affidavit also affirmatively misrepresented that the misdated articles were published in a Radiology journal article when in fact the Radiology journal article submitted as an exhibit to the Rule 131 affidavit was a different article than the misdated manuscripts. Also with respect to the Rule 131 affidavit, a request to use lab animals was submitted to show evidence of diligence when in fact the request to use lab animals was knowingly unrelated to the alleged invention of the '665 patent.

c. Misrepresentations during the First Reexamination of the '665 patent, Dr. Palmaz, his attorneys, and/or EGP (and others substantively involved in the patent prosecution) that the stent of the alleged invention had a smooth outer wall surface after expansion in order to distinguish over the prior art U.S. Patent No. 3,657,744, issued to Ersek (the "Ersek patent"), when in fact, it was known by Dr. Palmaz, his attorneys, and/or EGP that the stent had projecting edges when expanded.

d. Failing to adequately disclose the Ersek patent. Specifically, during prosecution of the '417 patent, a Reply Brief in an appeal to the Board of Patent Appeals and

Interferences of the PTO was filed by Dr. Palmaz in which he made arguments, through his attorneys, distinguishing the patent claims from the prior art. Affirmative statements were made about what the prior art did not show. However, the attorney representing Dr. Palmaz admittedly was aware of and had substantively considered the Ersek patent, yet wrongfully failed to inform the PTO that the Ersek patent taught the very features that were being represented as not taught by the prior art then being considered by the PTO.

e. For the reasons stated above and for the reasons that will be developed in discovery, the '762 and '417 patents are unenforceable under the doctrines of fraud, and/or inequitable conduct in the PTO.

35. For the reasons stated in paragraphs 34a-e, Cordis and EGP are barred by the equitable defense of unclean hands from any recovery for alleged infringement by ACS of the '762 and '417 patents.

COUNTERCLAIMS

By way of a counterclaim against Plaintiffs Cordis Corporation ("Cordis") and Expandable Grafts Partnership ("EGP"), Defendant Advanced Cardiovascular Systems, Inc. ("ACS") alleges as follows:

1. This counterclaim arises under the Federal Declaratory Judgment Act and the Patent Laws of the United States, and more particularly under Title 28 U.S.C. §§ 2201 and 2202, and Title 35 U.S.C. §§ 100, et. seq., respectively. Jurisdiction is based on Title 28 U.S.C. §§ 1338 and 2201.

2. Plaintiff Cordis alleges that it is a corporation organized and existing under the laws of the State of Florida having its principal places of business at 40 Technology Drive, Warren, New Jersey and at 14201 N.W. 60th Avenue, Miami Lakes, Florida.

3. Plaintiff EGP alleges that it is a partnership organized and existing under the laws of the State of Texas and having an address at 1500 NationsBank Plaza, 300 Convent Street, San Antonio, Texas 78230.

4. ACS is a California corporation having its principal place of business at 3200 Lakeside Drive, Santa Clara, California 95054.

5. Cordis and EGP have charged ACS with infringement of U.S. Patent Nos. 4,733,762 and 5,102,417, and have filed this suit against ACS in this Court for the alleged infringement.

6. ACS alleges that U.S. Patent No. 4,733,762, and the claims thereof are invalid, void, and unenforceable, and that ACS has not infringed and is not infringing any of said claims. As part of this allegation, ACS repeats and realleges and incorporates herein by reference, each of the allegations set forth in paragraphs 27-35 set forth above.

7. ACS alleges that U.S. Patent No. 5,102,417, and the claims thereof are invalid, void, and unenforceable, and that ACS has not infringed and is not infringing any of said claims. As part of this allegation, ACS repeats and realleges and incorporates herein by reference, each of the allegations set forth in paragraphs 27-35 set forth above.

PRAYER

WHEREFORE, ACS prays for an adjudication against Cordis and EGP as follows:

A. Cordis and EGP take nothing by reason of their Complaint and that all counts of the same be dismissed with prejudice;

B. The claims of the '762 and '417 patents be declared invalid and not infringed by ACS;

- C. The '762 and '417 patents be declared unenforceable due to inequitable conduct and/or fraud on the PTO;
- D. Cordis and EGP be barred from any recovery because of laches;
- E. Cordis and EGP be barred from any recovery because of the equitable defense of unclean hands;
- F. This case be declared exceptional under 35 U.S.C. § 285, and that ACS be awarded its reasonable attorney fees and expenses of litigation;
- G. ACS be awarded costs of this suit; and
- H. ACS be awarded such other and further relief as this Court shall deem just and proper.

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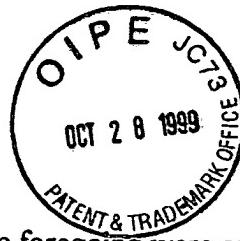
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Date: April 8, 1998

CERTIFICATE OF SERVICE



I hereby certify that two true and correct copies of the foregoing were served this
8th day of April, 1998 on counsel in the manner indicated:

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I hereby certify that a true and correct copy of the foregoing was served by U.S.

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